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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,684	03/20/2000	MICHAEL ANTHONY CAWTHORNE	00537/161002	7046

7590 02/25/2004  
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BOSTON, MA 02110

EXAMINER

ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/423,684	<b>Applicant(s)</b> CAWTHORNE ET AL.	
	<b>Examiner</b> Hope A. Robinson	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I (claims 1-37, H-D-Beta-Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH<sub>2</sub>) on November 19, 2003 is acknowledged. The traversal is on the grounds that the somatostatin and somatostatin analogs not be restricted. Applicant regards this election as a species election which is incorrect. The above is deemed an invention election, thus cancellation of the non-elected subject matter is suggested. It is very clear from the specification and claim 23 that the somatostatin and analogs thereof are structurally distinct. As the somatostatins have different structures, the function can vary, therefore are independent and patentably distinct. If applicant is willing to state on the record that a reference that teaches a specific somatostatin or analog thereof would either render obvious or anticipate all of the structures listed in claim 23 then the sequences can be rejoined. The MPEP in chapter 800 states that restrictions are proper if the invention is found to be independent and or distinct. Thus, the restriction requirement is proper and final.

### ***Claim Disposition***

2. Claims 33-37 have been canceled. Claims 1-32 are pending and are under examination.

### ***Claim Objection***

3. Claim 23 is objected to as the claims recites specific sequences without the corresponding sequence identifier (SEQ ID NO:).

Compliance with the sequence rules is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim recites "a method to decrease body weight in a patient" and there is no indication of a decrease by how much? Is this a reduction in a patient with excessive body weight and how long before desired results are obtained? See also claim 11.

Claims 12-22 have an improper sentence structure, where the claims recites "an non-insulin-dependent diabetic human" instead of "a non-insulin-dependent diabetic human".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103 (a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103 (a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103 (c) and potential 35 U.S.C. 102 (f) or (g) prior art under 35 U.S.C. 103 (a).

6. Claims 1, 4, 6, 8, 10-11 and 32 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Dunmore et al. (WO 96/35950, 14 November 1996) in view of Huang et al. (Supplement to Hypertension, vol. 19, no.1, pages 1-109, January 1992).

Dunmore et al. teach that somatostatin type-5 receptor agonists reduce hyperamylinamia. Dunmore et al. teach ligands selective for somatostatin type-5-receptor (SSTR-5, see claims 4 and 8) that are said to be effective in inhibiting release of amylin from pancreatic cells (see page 2 lines 18-21) thus reducing hyperamyliniemia. It is further indicated that "the presence of an abnormally high concentration of amylin in the blood, for example hyperamylinemia, has been found in obese patients (see claim 32 of the claim, page 1 lines 18-24 of the reference).

Dunmore et al. disclose pharmaceutical compositions comprising somatostatin agonists such as H-Cys-Phe-Phe-D-Trp-Lys-Thr-Phe-Cys-NH<sub>2</sub> (claim 11, see page 6 line 34 to page 7 line 6 of the reference). Dunmore et al. does not explicitly teach a method to decrease body weight.

However, Huang et al. teach that "hyperamylinamia is not simply a passive partner to

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hyperinsulinemia, but rather it acts as a causative mechanism of insulin resistance and associated metabolic derangements including obesity (claim 1, see page 107 of the reference). With regard to claims 6 and 10 the specification states that SSSTR-5 or SSSTR-2 means a compound which has a high affinity for example, a  $K_i$  of less than 1  $\mu\text{M}$  or less than 10 nM or less than 2 nM..., thus, it appears that the  $K_i$  is an intrinsic property.

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention as a whole because Dunmore et al. disclose that somatostatin type-5 receptor agonists reduce hyperamylinamia found in obese patients and Huang et al. teach that hyperamylinamia plays a causative role in producing obesity, thus one of skill in the art would be motivated to use somatostatin type-5 receptor agonist in the treatment of obesity. One of skill in the art would be motivated to combine the teachings of the references because Dunmore et al. provides a method to reduce obesity (body weight) using somatostatin by affecting hyperamylinamia. Thus, the claimed invention was within the skill of the art and is *prima facie* obvious.

### ***Conclusion***

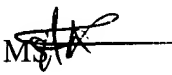
7. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (571) 272-0957. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:30 P.M. (EST).

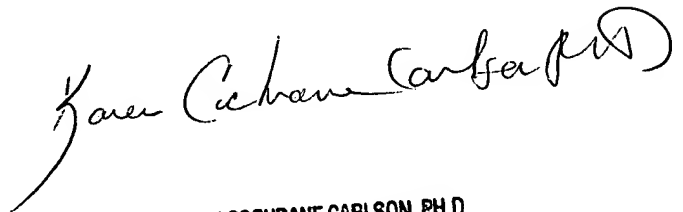
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (571) 272-0951.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS 

Patent Examiner



KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER